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SCHIFF HARDIN, LLP PATENT DEPARTMENT 6600 SEARS TOWER CHICAGO, IL 60606-6473			EXAMINER FRENEL, VANEL	
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/742,268
Filing Date: December 20, 2000
Appellant(s): ABRAHAM-FUCHS ET AL.

MAILED

OCT 18 2007

GROUP 3600

Alexander Burke
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed on July 31th, 2007 appealing from the Office action mailed January 3th, 2007.

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(1) Real Party in interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,354,299	FISCHELL et al.	3-2002
5,868,135	KAUFMAN et al.	2-1999

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-28 are rejected under 35 U.S.C. 103 (a) . This rejection is set forth in the prior Office Action mailed on 1/03/07. This rejection is set forth below as it appears in the previous Office Action mailed on 1/03/07.

Claims 1-28 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Fischell et al. (6,354,299) in view of Kaufman et al. (5,868,135).

(A) As per claim 1, Fischell discloses a method for allowing a patient, suffering from a neurological disease and receiving medication for said disease, to self-monitor the patient's actual state (See Fischell, Abstract; Col.6, lines 49-67 to Col.7, line 3), comprising the steps of:

providing a computer at a location readily accessible to a patient substantially on a daily basis for acquiring information from a patient (See Fischell, Col.9, lines 39-61);

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acquiring information, via an interactive procedure, from a patient wherein the acquired information is selected from a group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient (See Fischell, Col.15, lines 57-67 to Col.16, line 6); providing an expert system accessible by the computer (See Fischell, Col.17, lines 10-55);

Fischell does not explicitly disclose that the method having providing said acquired patient information to said expert system for processing thereby, and determining, from the acquired information, at least one quantified indicator describing the state of the patient suffering from a neurological disease which is treated with medication; and

providing said computer with an output device and making said quantified indicator available to the patient via said output device.

However, these features are known in the art, as evidenced by Kaufman. In particular, Kaufman suggests that the method having providing said acquired patient information to said expert system for processing thereby, and determining, from the acquired information, at least one quantified indicator describing the state of the patient suffering from a neurological disease which is treated with medication (See Kaufman, Col.4, lines 26-60); and

providing said computer with an output device and making said quantified indicator available to the patient via said output device (See Kaufman, Fig.4; Col.6, lines 36-67).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the features of Kaufman within the system of Fischell with the motivation of detecting when the individual should receive predetermined medication (See Kaufman, Col.3, line 10-11).

(B) As per claim 2, Kaufman discloses a method wherein said information comprises information characterizing a motor function of said patient, and wherein the step of conducting an interactive procedure comprises conducting software-controlled motor function exercises for identifying negative and positive effects of said medication on said patient's state, and quantifying said negative and positive effects for processing by said expert system for producing said quantified indicator (See Kaufman, Col.7, lines 1-35).

The combination for combining the respective teachings of Fischell and Kaufman are as discussed above in the rejection of claim 1, and incorporated herein.

(C) As per claim 3, Kaufman discloses a method wherein said information is information characterizing a verbal communication ability of said patient, and wherein conducting an interactive procedure comprises acoustically acquiring speech from said patient and assessing said speech with a speech assessment system in said computer containing speech recognition algorithms and a phonetic data bank to obtain an information value quantifying negative and positive effects of said medication on said speech, and supplying said information value to said expert system for processing by

said expert system for producing said quantified indicator (See Kaufman, Col.4, lines 23-60).

The combination for combining the respective teachings of Fischell and Kaufman are as discussed above in the rejection of claim 1, and incorporated herein.

(D) As per claim 4, Fischell discloses a method wherein said information is information characterizing cognitive abilities of the patient, and wherein conducting an interactive procedure comprises generating questions by said computer and requiring a response from said patient to the respective questions and, from said responses, generating an information value quantifying negative and positive effects of said medication on said cognitive abilities of the patient, and supplying said information value to said expert system for processing in said expert system to produce said quantified indicator (See Fischell, Col.3, lines40-67).

(E) As per claim 5, Kaufman discloses a method comprising acoustically entering said responses from said patient into said computer (See Kaufman, Fig.4, Col.6, lines 30-60).

The combination for combining the respective teachings of Fischell and Kaufman are as discussed above in the rejection of claim 1, and incorporated herein.

(F) As per claim 6, Kaufman discloses a method comprising manually entering said responses from said patient into said computer (See Kaufman, Col.6, lines 30-60).

The combination for combining the respective teachings of Fischell and Kaufman are as discussed above in the rejection of claim 1, and incorporated herein.

(G) As per claim 7, Fischell discloses a method comprising entering additional information into said computer in said interactive procedure characterizing a subjective state of health of said patient (See Fischell, Abstract; Col.25, lines 1-31).

(H) As per claim 8, Fischell discloses a method comprising obtaining a quantified information value representing said information in said interactive procedure, and storing, as stored information with respect to time, at least one of said quantified indicator, said information and said quantified information value after each interactive procedure (See Fischell, Col.34, lines 9-53).

(I) As per claim 9, Fischell discloses a method comprising providing said stored information to said expert system, and producing in said expert system an evaluation regarding dosage of said medication based on said stored information and making said evaluation available to the patient at said output device (See Fischell, Col.33, lines 36-67).

(J) As per claim 10, Fischell discloses a method wherein said stored information includes said quantified indicator, and wherein said expert system produces said evaluation from an analysis of a curve relative to time of the respective quantified

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indicators obtained after each interactive procedure (See Fischell, Col.34, lines 9-53).

(K) As per claim 11, Fischell discloses a method further comprising making said chronological curve available to said patient as a displayed curve at said output device (See Fischell, Col.25, lines 1-31).

(L) As per claim 12, Fischell discloses a method comprising storing said evaluation in a memory accessible by said computer (See Fischell, Col.18, lines 24-38).

(M) As per claim 13, Fischell discloses a method comprising establishing communication between said computer and a physician located remote from said computer, and informing said physician of at least one of said quantified indicator and said evaluation and said information, as transmitted information (See Fischell, Col.32, lines 55-67 to Col.33, line 35).

(N) As per claim 14, Fischell discloses a method comprising transmitting therapy instructions from said physician to said computer based on an examination of said transmitted information, and making said therapy instructions available to the patient at said output device (See Fischell, Col.33, lines 36-67 to Col.34, line 26).

(O) As per claim 15, Fischell discloses a method comprising formulating said quantified indicator as a number (See Fischell, Col.20, lines 37-49).

(P) As per claim 16, Fischell discloses a method comprising formulating said quantified indicator as a statement (See Fischell, Col.20, lines 50-67 to Col.21, line 22).

(Q) As per claim 17, Fischell discloses a system for allowing a patient suffering from a neurological disease and receiving medication for treating said disease, to self-monitor a state of the patient, comprising: a computer readily accessible by the patient disposed at a location at which said patient is present substantially on a daily basis (See Fischell, Col.9, lines 39-61);

at least one software program installed in said computer for operating said computer to execute an interactive procedure with said patient to obtain information selected from the group consisting of information characterizing a motor function of the patient, information characterizing verbal communication abilities of the patient, and information characterizing cognitive abilities of the patient (See Fischell, Col.15, lines 57-67 to Col.16, line 6);

an input unit connected to said computer for use by said patient during said interactive procedure for acquiring said information (See Fischell, Col.9, lines 39-61);.

Fischell does not explicitly disclose that the system having an expert system accessible by said computer able to receive said information and produce a quantified indicator from said information and making said quantified indicator available to said computer; and

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an output unit connected to said computer for providing said quantified indicator to the patient.

However, these features are known in the art, as evidenced by Kaufman. In particular, Kaufman suggests that the system having an expert system accessible by said computer able to receive said information and produce a quantified indicator from said information and making said quantified indicator available to said computer (See Kaufman, Col.4, lines 26-60);

and

an output unit connected to said computer for providing said quantified indicator to the patient (See Kaufman, Fig.4; Col.6, lines 36-67).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the features of Kaufman within the system of Fischell with the motivation of detecting when the individual should receive predetermined medication (See Kaufman, Col.3, line 10-11).

(R) As per claim 18, Fischell discloses a system wherein said information is information characterizing a motor function of the patient, and wherein said input unit is a manually operated input unit, and wherein said software program operates said computer to execute motor function test exercises and produces a quantified information value quantifying negative and positive effects of said medication on said motor function and makes said quantified information value available to said expert system (See Fischell, Col.21, line 19-67).

(S) As per claim 19, Kaufman discloses a system wherein said information is information characterizing verbal communication abilities of the patient, and wherein said input unit is an acoustical input unit, and wherein said software program assesses speech made by said patient into said input unit using speech algorithms and a phonetic data bank, and produces a quantified information value representing said verbal communication abilities, and makes said quantified information value available to said expert system (See Kaufman, Fig.112; Col.6, lines 61-67).

The combination for combining the respective teachings of Fischell and Kaufman are as discussed above in the rejection of claims 1 and 17, and incorporated herein.

(T) As per claim 20, Kaufman discloses a system wherein said information is information characterizing cognitive abilities of the patient and wherein said software operates said computer to present questions to said patient and to receive responses from said patient, and produces a quantified information value from said responses quantifying negative and positive effects of said medication on said cognitive abilities, and makes said quantified information value available to said expert system (See Kaufman, Col.5, lines 14-45).

The combination for combining the respective teachings of Fischell and Kaufman are as discussed above in the rejection of claims 1 and 17, and incorporated herein.

(U) As per claim 21, Fischell discloses a system comprising a further software program for operating said computer to obtain additional information from said patient characterizing a subjective state of health of said patient (See, Fischell Col.1, lines 19-57 Col.3, lines 5-39).

(V) As per claim 22, Fischell discloses a system wherein said software program in information, and further comprising a memory accessible by said computer and by said expert system for storing, as stored information relative to time, at least one of said quantified indicator, said information and said quantified information value after each interactive procedure (See Fischell, Col.36, lines 31-67).

(W) As per claim 23, Fischell discloses a system wherein said expert system produces an evaluation from said stored information with regard to a dosage of said medication (See Fischell, Col.15, lines 43-67).

(X) As per claim 24, Fischell discloses a system wherein said stored information includes said quantified indicator, and wherein said expert system produces said evaluation by analyzing a chronological curve of respective quantified indicators obtained from successive interactive procedures (See Fischell, Fig.8, Col.21, lines 35-67).

(Y) As per claim 25, Fischell discloses a system wherein said computer displays

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said chronological curve as a displayed curve at said output device (See Fischell, Fig.8; Col.21, lines 35-67; Col.25, lines 1-31).

(Z) As per claim 26, Fischell discloses a system further comprising a transmission link from said computer to an external computer located remotely from said computer for transmitting at least one of said evaluation and said quantified indicator to said external computer (See Fischell, Col.26, lines 8-40).

(AA) As per claim 27, Fischell discloses a system wherein said software operates said computer to formulate said quantified indicator as a number (See Fischell, Fig.8; Col.21, lines 35-67 to Col.22, line 18).

(BB) As per claim 28, Fischell discloses a system wherein said software operates said computer to formulate said quantified indicator as a statement (See Fischell, Col.21, lines 35-67 to Col.22, line 18).

(10) Response to Argument

In the Appeal Brief filed on 7/31/07, Appellant makes the following arguments:

(i) Fischell and Kaufman when taken alone or in combination do not make the present claimed invention unpatentable.

(ii) Fischell fails to teach "acquiring information by using interactive procedures".

(III) Fischell neither discloses nor suggests any structural elements that are able to produce the claimed "quantified indicator" that is used in self-monitoring the patient's actual state.

(iv) Fischell fails to disclose or suggest "providing said acquired patient information to said expert system for processing thereby, and determining, from the acquired information, at least one quantified indicator describing the state of the patient suffering from a neurological disease which is treated with medication.

(v) Neither Kaufman nor Fischell discloses the patient's motor skills, verbal communication ability and cognitive ability.

(vi) Neither Kaufman nor Fischell discloses "providing said computer with an output device and making said quantified indicator available to the patient via said output device.

(vii) There is no reason or motivation to combine the systems of Fischell and Kaufman for they are concerned with totally different methods of acquiring patient information.

(viii) Fischell and Kaufman neither discloses nor suggests "a method for allowing a patient, suffering from a neurological disease and receiving medication for said disease, to self-monitor the patient's actual state" such that the patient may be provided with a "quantified indicator describing the state of the patient suffering from a neurological disease which is treated with medication.

(ix) The combination of Fischell and Kaufman fails to produce a method that allows a patient to self-monitor their actual state based on interactive verbal response.

(x) The combination of Fischell and Kaufman neither discloses nor suggest "acquiring information, via an interactive procedure, from a patient wherein the acquired information is selected from a group consisting of information characterizing a motor function of the patient, information characterizing a verbal communication ability of the patient, and information characterizing cognitive abilities of the patient.

Examiner will address Appellant argumentS and related points in sequence as they appear in the Brief.

(I) With respect to Appellant first point of argument, Examiner respectfully submitted that obviousness is not determined on the basis of the evidence as a whole and the relative persuasiveness of the arguments. See *In re Oetiker*, 977F. 2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Hedges*, 783F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir.1992); *In re Piaseckii*, 745 F.2d 1468, 1472, 223 USPQ 785, 788

(Fed. Cir.1984); In *re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976). Using this standard, the Examiner respectfully submits that he has at least satisfied the burden of presenting a prima facie case of obviousness, since he has presented evidence of corresponding claim elements in the prior art and has expressly articulated the combinations and the motivations for combinations that fairly suggest Appellant's claimed invention. Note, for example, in the instant case, the Examiner respectfully notes that each and every motivation to combine the applied references are accompanied by select portions of the respective reference(s) which specially support that particular motivation and /or an explanation based on the logic and scientific reasoning of one ordinarily skilled in the art at the time of the invention that support a holding of obviousness. As such, it is not seen that the Examiner's combination of references is unsupported by the applied prior art of record. Rather, it is respectfully submitted that explanation based on the logic and scientific reasoning of one of ordinarily skilled in the art at the time of the invention that support a holding of obviousness has been adequately provided by the motivations and reasons indicated by the Examiner, *Ex parte Levengood*, 28 USPQ2d 1300(Bd. Pat. App.& Inter., 4/22/93). Therefore, the combination of references is proper and the rejection is maintained.

In addition, the Examiner recognizes that references cannot be arbitrarily altered or modified and that there must be some reason why one skilled in the art would be motivated to make the proposed modifications. However, although the Examiner agrees that the motivation or suggestion to make modifications must be articulated, it is respectfully contended that there is no requirement that the motivation to make

modifications must be expressly articulated within the references themselves.

References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures, *In re Bozek*, 163 USPQ 545 (CCPA 1969).

The Examiner is concerned that Appellant apparently ignores the mandate of the numerous court decisions supporting the position given above. The issue of obviousness is not determined by what the references expressly state but by what they would reasonably suggest to one of ordinary skill in the art, as supported by decisions in *In re DeLisle* 406 Fed 1326, 160 USPQ 806; *In re Kell, Terry and Davies* 208 USPQ 871; and *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988) (citing *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1988)). Further, it was determined in *In re Lamberti et al*, 192 USPQ 278 (CCPA) that:

- (i) obviousness does not require absolute predictability;
- (ii) non-preferred embodiments of prior art must also be considered; and
- (iii) the question is not express teaching of references, but what they would suggest.

According to *In re Jacoby*, 135 USPQ 317 (CCPA 1962), the skilled artisan is presumed to know something more about the art than only what is disclosed in the applied references. In *In re Bode*, 193 USPQ 12 (CCPA 1977), every reference relies to some extent on knowledge of persons skilled in the art to complement that which is disclosed therein.

According to *Ex parte Berins*, 168 USPQ 374 (Bd. Appeals), there is no statutory limitation as to the number of references that may be used to demonstrate obviousness...not what references expressly state but what they would reasonably suggest to one of ordinary skill in the art. In *In re Conrad*, 169 USPQ 170 (CCPA),

obviousness is not based on express suggestion, but what references taken collectively would suggest.

Nonetheless, it is respectfully submitted that an explanation based on logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention that support a holding of obviousness has been adequately provided by the motivations and reasons indicated by the Examiner in the previous Office Action, *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter., 4/22/93).

Furthermore, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The skilled artisan would not consider the prior art embodiments in a vacuum, but would have had the motivation to combine the advantageous features of the prior art in the manner purported by the Examiner for the reasons and motivations given in the prior Office Action. Thus, the teachings of Fischell and Kaufman when considered with the knowledge that is generally available to one of ordinary skill in the art make obvious the limitations that Appellant disputes. Therefore, Appellant's argument is not persuasive and the rejection is hereby sustained.

(ii) With respect to Appellant second argument, Examiner respectfully submitted that He relied upon the clear teaching of Kaufman by stating "Also carried on the surface 108 is a loudspeaker 110 which is coupled to the voice synthesis and recognition unit 36 discussed previously. A hands-free microphone 112 is also provided, coupled to the voice synthesis and recognition unit 36, for purposes of audio input by the patient P"

See Abstract; Fig.4; Col.6, lines 30-65 specifically lines 61-65 which correspond to Appellant's claimed feature. Therefore, Appellant's argument is not persuasive and the rejection is hereby sustained.

(iii) With respect to Appellant third argument, Examiner respectfully submitted that He relied upon the clear teaching of Kaufman in Col.4, lines 26-52 for such limitation and corresponded to Appellant's claimed feature. Therefore, Appellant's argument is not persuasive and the rejection is hereby sustained.

(iv) With respect to Appellant fourth argument, Examiner respectfully submitted that He relied upon the clear teaching of Kaufman whom suggested "a voice synthesizer circuitry for the purpose of generating audible messages. The messages can remind the patient of specific, preprogrammed, tasks to be performed at predetermined times. For example, the voice synthesizer circuitry, in combination with the control unit, can remind the patient that it is time to take medication or carry out a monitoring test such as taking a temperature or a blood pressure" See Col.2, lines 20-27 which correspond to Appellant's claimed feature. Therefore, Appellant's argument is not persuasive and the rejection is hereby sustained.

(v) With respect to Appellant fifth argument, Examiner respectfully submitted that He relied upon the clear teaching of Kaufman whom suggested "the voice synthesizer circuitry can also be used to communicate with the patient when the preprogrammed

schedule needs to be varied. That circuitry can also prompt verbal responses usable to determine general patient condition" See Kaufman, Col.2, lines 28-31 which correspond to Appellant claimed feature. Therefore, Appellant's argument is not persuasive and the rejection is hereby sustained.

(vi) With respect to Appellant sixth argument, Examiner respectfully submitted that He relied upon the clear teaching of Kaufman for such a feature See Col.4, lines 40-47. Therefore, Appellant's argument is not persuasive and the rejection is hereby sustained.

(vi) With respect to Appellant seventh argument, it is respectfully submitted that Appellant's argument that is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the Applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the primary reference, Fischell is directed to four different modalities for stopping the progression of a neurological event such as an epileptic seizure once it has been detected. A preferred method is to provide a responsive stimulation electrical signal, a second is to release medication in response to the detection of an event, a third method is to an electrical short circuit in the vicinity of the epileptic focus to prevent occurrence of a full epileptic seizure and a fourth method is the application of a sensory input through normal sensory pathways, and the secondary reference, Kaufman, is drawn to a voice

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synthesizer circuitry which can also be used to communicate with the patient when the preprogrammed schedule needs to be varied. That circuitry can also prompt verbal responses usable to determine general patient condition. However, Kaufman is reasonably pertinent to the particular problem with which Applicant was concerned because they both are in the same field of endeavor. Therefore, Appellant's argument is not persuasive and the rejection is hereby sustained.

(viii) With respect to Appellant's eighth, ninth and tenth arguments, Examiner respectfully noted that the arguments are similar as the previous responses above, are therefore follow the same guidelines and incorporated herein. Furthermore, Appellant's remaining arguments rely upon those arguments addressed above, and are likewise moot for the same reasons set forth in the preceding responses.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Vanel Frenel (V.F)

Patent Examiner

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October 10, 2007

CONFEREES:

Zeender Ryan Florian

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Art Unit 3627


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